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Support for Amendment

Independent claims 1 and 21 are amended to characterize the anionic surfactant as a sulfate. This amendment is supported by the specification at page 6, lines 12-13.

Claim 21 is amended by replacing a comma with a semi colon.

No new matter is introduced by this amendment, and entry thereof is requested. Upon entry, claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31, and 33 are active in this application.

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REMARKS

The amendment to independent claims 1 and 21 characterizes the anionic surfactant as a sulfate. The outstanding Office Action contends that the soybean lecithin described by European Patent No. EP 0 685 556 to *Ghazarian et al.* is an anionic surfactant. See the outstanding Office Action at page 3, lines 1-3, and page 7, lines 12-20. Independent claims 1 and 21 now clearly characterize the anionic surfactant component in a manner that excludes an interpretation that it includes soybean lecithin.

Enclosed with this amendment is a Supplemental Declaration Under 37 C.F.R. §1.131 signed by Richard Lomneth, Ph.D., an inventor of the above-identified patent application. According to the outstanding Office Action, the Rule 131 Declaration mailed on March 31, 2005 (hereinafter "the first Rule 131 Declaration") has essentially been disregarded on the grounds that "the laboratory notebook pages do not contain any information that the purified lecithin described therein is not from the animal source as encompassed by the present application and claims." See the outstanding Office Action at page 9, lines 3-7. It is submitted that paragraph 4 of the first Rule 131 Declaration sufficiently characterizes the lecithin reported in Exhibit A as lecithin from a non-animal source. In order to further substantiate the fact that the lecithin reported in Exhibit A is from a non-animal source, the Supplemental Declaration Under 37 C.F.R. §1.131 (hereinafter "the Supplemental Rule 131 Declaration") is enclosed with this Amendment. The Supplemental Rule 131 Declaration clearly states that the lecithin referred to in the notebook pages of Exhibit A of the first Rule 131 Declaration is lecithin from a non-animal source.

The outstanding Office Action includes several prior art-based rejections. The following discussion addresses each of the prior art-based rejection in turn.

Rejection over European Patent No. 0 685 556 (*Ghazarian et al.*)

Claims 1, 2, 4, 11, 14, 21, 22, 24-26, and 28-30 stand rejection under 35 U.S.C. § 102(b) over *Ghazarian et al.* This rejection is traversed.

Ghazarian et al. fail to disclose an aqueous ready-to-use semen extender composition containing about 0.0001 wt.% to about 1 wt.% of anionic surfactant to reduce ice crystal formation during freezing of the composition, wherein the anionic surfactant comprises a sulfate according to the present invention. Furthermore, *Ghazarian et al.* fail to describe a method for

manufacturing an aqueous ready-to-use semen extender composition wherein the semen extender composition comprises about 0.0001 wt.% to about 1 wt.% of anionic surfactant to reduce ice crystal formation during freezing of the composition, wherein the anionic surfactant comprises a sulfate according to the presently claimed invention.

The outstanding Office Action at page 7 contends that soybean lecithin is an anionic surfactant since it bears a negative charge of the group PO_4^- . It pointed out that soybean lecithin is clearly not a sulfate as required by independent claims 1 and 21.

Futhermore, the outstanding Office Action on page 7 contends that "TRIS is also an emulsifying agent as taught by MERCK, for example: see page 1664 of The MERCK INDEX. 1996. 12th edition." According to the MERCK INDEX, TRIS is 2-amino-2-hydroxymethyl-1-3-propanediol. Clearly, TRIS is not a sulfate as required by the presently claimed invention.

Accordingly, the claimed invention is not anticipated by *Ghazarian et al.*, and withdrawal of this rejection is requested.

Rejection over U.S. Patent No. 6,368,786 (*Saint-Ramon et al.*)

Claim 1, 2, 4-6, 8, 11, 13, 14, 21, 22 stand rejected under 35 U.S.C. § 102(e) over *Saint-Ramon et al.* This rejection is traversed.

Enclosed with this amendment is a Supplemental Rule 131 Declaration. The Supplemental Rule 131 Declaration demonstrates that the lecithin referred to in Exhibit A of the first Rule 131 Declaration is soybean lecithin. Furthermore, the Supplemental Rule 131 Declaration clearly states that the lecithin referred to in Exhibit A of the first Rule 131 Declaration is lecithin from a non-animal source.

In view of the enclosed Supplemental Rule 131 Declaration and the first Rule 131 Declaration, it is clear that there was a reduction to practice of the presently claimed invention prior to May 14, 1999.

In view of the attached Supplemental Rule 131 Declaration and the first Rule 131 Declaration, it is submitted that *Saint-Ramon et al.* does not qualify as prior art and withdrawal of the rejection over *Saint-Ramon et al.* is requested.

Rejection under 35 U.S.C. § 103

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31, and 33 stand rejected under 35 U.S.C. § 103(a) over *Ghazarian et al.* or *Saint-Ramon et al.*, and U.S. Patent No. 3,444,039 to *Rajamannan*, U.S. Patent No. 6,130,034 to *Aitken*, U.S. Patent No. 6,140,121 to *Ellington et al.*, C. Helleman, and E. Giegoux, Deep Freezing of Rabbit Sperm, Effect of a Surfactant on Fertilizing Capacity, *Zuchthyg.*, 23, 33-37 (1988)(*Hellemann et al.*) This rejection is traversed.

In view of the above comments, *Saint-Ramon et al.* are not available as prior art. Accordingly, withdrawal of this rejection as it is based upon *Saint-Ramon et al.* is requested.

As discussed previously, *Ghazarian et al.* fail to disclose an aqueous ready to use semen extender composition comprising about 0.0001 wt.% to about 1 wt.% of anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention. It is submitted that the references relied upon in the outstanding Office Action would not have suggested modifying *Ghazarian et al.* to include an anionic surfactant comprising a sulfate according to the present invention.

Ghazarian et al. are directed to a vehicle for nonautonomous microorganisms of the animal kingdom to be kept alive outside their natural environment with a view to human interventions. The vehicle includes an aqueous medium comprising nutrition agents, buffers and mineral salts, and a protective product formed as a support for embryonic growth by a living organism, wherein the protective product is a lecithin extracted from soy seeds and introduced into the aqueous medium upon formation of the vehicle. See the English language translation of *Ghazarian et al.* on page 2, lines 1-17, and page 3, lines 20-27.

As discussed above, *Ghazarian et al.* fail to disclose a composition containing about 0.0001 wt.% to about 1 wt.% of anionic surfactant, comprising a sulfate, to reduce ice crystal formation during freezing of the composition. Furthermore, *Rajamannan*, *Aitken*, *Ellington et al.*, and *Hellemann et al.* would not have suggested modifying *Ghazarian et al.* to include about 0.0001 wt.% to about 1 wt.% of anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the presently claimed invention.

Rajamannan appears to be relied upon in the outstanding Office Action for the disclosure of buffering to a pH of 6 to 7.5 and for the disclosure of sodium citrate as a buffering agent. See *Rajamannan* at column 3, line 30 and lines 41-47. It is pointed out that *Rajamannan* is directed at an egg yolk containing composition. See *Rajamannan* at column 1, lines 13-19, and the

example disclosing the presence of egg yolk solids. Accordingly, *Rajamannan* is representative of prior art compositions that are based on the use of egg yolk. In contrast, the present invention is an improvement over prior art egg yolk-based compositions. Furthermore, *Rajamannan* fails to disclose or suggest the use of about 0.0001 wt.% to about 1 wt.% anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention.

It appears that the outstanding Office Action relies upon *Aitken* for the disclosure of an anti-oxidant. *Aitken* refers to an anti-oxidant such as vitamin E at column 1, line 50. It is pointed out, however, that *Aitken* is also directed at an egg yolk-containing system. See *Aitken* at column 1, lines 28-38. Clearly, *Aitken* is similarly representative of a prior art composition containing egg yolk. In contrast, the present invention is directed at a semen extender composition that is substantially free of animal products such as egg yolk. As discussed in the specification of the above-identified patent application beginning at page 3, line 23, it is believed that animal products, such as egg yolk, may contain nonpathogenic organisms or pathogenic organisms harmful to the host or cell provided in contact with the animal product. Accordingly, the present invention is directed at an improvement over those compositions that contain animal product. The outstanding Office Action fails to explain why one having ordinary skill in the art would look to a disclosure relating to the use of raw egg yolk for a suggestion to modify a composition that is free of raw egg yolk.

It is submitted that raw egg yolk contains a large number of various components and is a much more complicated system than the semen extender composition that does not contain raw egg yolk according to the present invention. Accordingly, the disclosure of the use of an anti-oxidant in a raw egg containing semen extender composition according to *Aitken* in no way suggests the use of an anti-oxidant in a non-raw egg containing semen extender composition.

Nevertheless, the outstanding Office Action fails to explain why one having ordinary skill in the art would have received a suggestion from *Aitken* to modify *Ghazarian et al.* to include about 0.0001 wt.% to about 1 wt.% anionic surfactant comprising a sulfate to reduce ice crystal formation during freezing of the composition according to the present invention.

The outstanding Office Action appears to rely on *Ellington et al.* for the disclosure of various buffers such as EDTA and TRIS. See *Ellington et al.* at column 16, lines 52-63, and column 19, line 28. The outstanding Office Action additionally refers to *Ellington et al.* for the

disclosure of a balanced culture medium such as M199 at column 16, line 59, and contends that medium M199 suggests the use of polyoxyethylene sorbitan (Tween 80). It is submitted that Tween 80 is provided in medium M199 to help dissolve the other components in medium M199. There is no disclosure by *Ellington et al.* or ATCC Catalogue (Page 522) that Tween 80 can be useful for reducing ice crystal formation during freezing of a semen extender composition. One having ordinary skill in the art would not have received any suggestion from *Ellington et al.* or ATCC Catalogue (Page 522) that the incorporation of Tween 80 into the composition described by *Ghazarian et al.* would have any benefit for reducing ice crystal formation during freezing according to the present invention.

The reliance upon *Ellington et al.* and ATCC Catalogue (Page 522) is an example of the use of impermissible hindsight. There must be a suggestion to combine the references or make the modifications to achieve a *prima facie* case of obviousness. It is not enough to simply pick and choose various components from several references. The outstanding Office Action fails to explain why one having ordinary skill in the art would be motivated to select Tween 80 from the lengthy list of components identified in balanced culture M199, and then add that component to the composition described by *Ghazarian et al.* Nevertheless, it is pointed out that Tween 80 is an example of a nonionic surfactant. There is no suggestion by *Ellington et al.* that an anionic surfactant comprising a sulfate can be used to reduce ice crystal formation during freezing according to the present invention.

Hellemann et al. are apparently relied upon in the outstanding Office Action for the disclosure of sodium laurel sulfate in a composition intended for rabbit semen. See the abstract of *Hellemann et al.* Similar to *Rajamannan* and *Aitken*, *Hellemann et al.* are directed at compositions containing raw egg. Accordingly, *Hellemann et al.* are yet another example of a representative prior art composition that relies upon the use of raw egg yolk. In contrast, the present invention is directed at an improvement over those compositions that are based upon animal products such as raw egg yolk. The Examiner's attention is directed to the specification at, for example, page 3, line 8 through page 4, line 2. It is submitted that one having ordinary skill in the art would not have looked to *Hellemann et al.* for modifying a composition that does not contain raw egg yolk. Furthermore, the outstanding Office Action fails to provide a sufficient reason to explain why one having ordinary skill in the art would modify *Ghazarian et al.* in view of the disclosure by *Hellemann et al.* to achieve the presently claimed invention.

The outstanding Office Action on page 6, merely states "the reference by Hellemann et al. teaches the use of surfactant sodium lauryl sulfate in the composition intended for animal semen preservation (see abstract)." However, *Hellemann et al.* fail to explain why one having ordinary skill in the art would be motivated to include sodium lauryl sulfate in a composition for freezing rabbit semen. Furthermore, one having ordinary skill in the art would not, from reading *Hellemann et al.*, understand why sodium lauryl sulfate would be included in a raw egg yolk-base composition, and would certainly not receive a suggestion to include sodium lauryl sulfate in a semen extender composition that is substantially free of animal products. *Hellemann et al.* clearly provide no suggestion on how to modify a composition that is substantially free of raw egg yolk.

In view of the comments, the presently claimed invention would not have been obvious from *Ghazarian et al.*, *Saint-Ramon et al.*, *Rajamannan*, *Aitken*, *Ellington et al.*, and *Hellemann et al.* Accordingly, withdrawal of this rejection is requested.

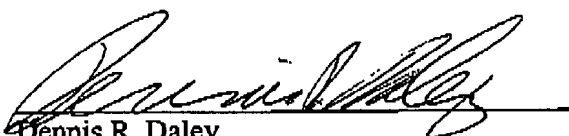
It is believed that this application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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